

Clinicianless Training in Autism Treatment: An Adaptive Online Parent Education Program

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SUMMARY OF KEY INFORMATION:

This section is to give you key information to help you decide whether or not to volunteer for a research study focused on the use of a smartphone app designed to train parents in how to use an early autism intervention called Pivotal Response Treatment (PRT) with their child with autism spectrum disorder (ASD).

This research is being funded by the Department of Defense's Congressionally Directed Medical Research Program - Autism Research Program.

If you decide to participate, you will be asked to:

- Complete some initial developmental survey questions about your child
- Record a 5-minute video of you interacting with your child
- Learn a motivation-based autism intervention known as Pivotal Response Treatment (PRT) through 8 weekly lessons that each last about 20-30 minutes
- After each lesson, use this app to record a 5-minute video of you practicing the PRT strategies with your child
- Review your video so that you can learn from your own performance
- Re-complete the same survey questions about your child and record a final video after the program is over

Time Commitment & Compensation: The project will take 8 weeks total, plus a final assessment 2-3 months after it is completed. In total, you have the possibility of being compensated up to a total of \$90:

- The overall expected time commitment for the initial survey questions and recording some parent-child videos is about 1-2 hours. You will be compensated \$25 for your time completing these.
- Each week, your expected time commitment is about 1 hour to complete the lesson. This includes 20-30 minutes to view the weekly lesson, 5-10 minutes to review the main points, 5 minutes to record your practice PRT video with your child, and 15-30 minutes to review your performance. You will be compensated \$5 for recording and submitting each video.
- You will also be encouraged to implement PRT with your child for 1 hour daily outside of the formal lesson time (7 hours a week)
- The time commitment to re-complete the survey questions and final parent-child videos is about 1-2 hours. You will be compensated another \$25 for completing these.

While benefits are not guaranteed, it is anticipated that families who participate in this research project will increase parent mastery of PRT strategies and child language, social, and developmental skills while also helping our research team evaluate the effectiveness of using this app for parent training. In some cases, the primary risk is that children may temporarily become frustrated when initially encouraged to work on their language skills. For a complete description of benefits and risks, refer to the detailed consent information in subsequent sections.

PURPOSE:

Your child is being asked to participate in a research study. The purpose of the study is to evaluate the use of a new, experimental smartphone application used as an instructional tool as a means to teach you the strategies of the highly effective, motivation-based autism intervention model (Pivotal Response Treatment). We are partnering with a software company, Novacoast Inc., to create and evaluate this app. Novacoast has significant experience creating secure, user-friendly smart phone applications.

There are currently challenges with getting the latest scientifically supported treatments in the hands of all families that need it. Historically, in order for families to benefit, they needed to live close to a major autism center and have adequate health insurance or financial means to pay professionals for these treatments. This project will evaluate if an app-based training program can help address this program by eliminating the need for a live therapist to receive high quality training. Although all families will receive the same PRT training lessons, we will also be exploring if certain features help families learn the techniques and strategies faster by assigning families to different versions of the app with different training components.

PROCEDURES:

Getting Started: If you decide to participate and also allow your child to participate, we will first have you complete our intake process, which consists of a number of background information forms and developmental surveys so that we can get to know you and your child's profile and monitor improvements. They will ask about your child's autism symptoms,

skill use around the house, and language. We will also have you record a couple of 5-minute videos of you and your child engaged in two separate play activities together. These videos will be recorded through this app and will be securely sent to our research team. Because this is a lengthy process, you will be compensated \$25 for completing these steps.

Pivotal Response Treatment Weekly Lessons: After the intake is completed, you will complete eight weekly lessons that will teach you the strategies of the PRT intervention model. Each lesson is about 20-30 minutes long and consists of key points, lesson slides, video examples, and brief knowledge checks. The eight lessons are summarized below:

Summary of the Eight App-Based PRT Lessons

The ABCs of PRT

An overview of PRT and its underlying behavioral and motivational strategies. This lesson focuses on understanding the antecedent, behavior, consequence sequence of PRT learning opportunities and briefly describes all components

Child Choice & Task Variation

The concept of following the child's lead, varying the activity, and using their preferred activities and interests as the focus for PRT learning opportunities

Child Attention & Clear Opportunities

The importance of obtaining the child's attention prior to delivering a clear, simple learning prompt

Contingency & Reinforced Attempts

The concept of immediately and contingently reinforcing any reasonable effort (not just perfect responses) to a prompted language attempt.

Natural Reinforcement

Use of logically related, natural reinforcers that are directly related to the child's verbal response.

Maintenance & Acquisition Tasks

A blend of easy, previously or nearly mastered learning opportunities to maximize motivation with more challenging, new concepts to promote more complex language acquisition

Social Activities & Reinforcement

Using social activities based on existing child interests to increase social motivation and engagement over time

Summary and Frequently Asked Questions

Reviews common questions and concerns raised by parents enrolled in PRT trials. Addresses strategies to respond to a lack of child responsiveness, slower than expected language development, and the presence of behavioral challenges.

Record a PRT Practice Video: After each lesson, you will be asked to record a 5-minute video of you practicing PRT in a brief play session with your child, using the strategies that you have learned in the lessons you have completed thus far. These videos are encrypted and securely shared with our research team through the app.

PRT Practice Video Review: After you record each video with your child, you will be asked to review your performance as a means to learn from your administration. You may also be asked some questions about what you observed.

Post-Project: After you complete all lessons, you have the ability to view past lessons, video examples, and your own video performances. 2-3 months after finishing the last PRT lesson, you will be invited to complete the developmental survey measures and record some final parent-child interaction videos.

Measuring Change: Our research team will examine the videos we receive and analyze them carefully to look at changes in PRT use and child responses. We will also compare the developmental survey results before and after participation in the project to assess for improvements. Finally, we will track how often you use the app to review past and current lessons. Participants will be notified via email when the project's clinical research results are published in a research journal. Individual family research results will not be disclosed to participants.

Time Commitment: The total time commitment for this study is estimated to be 3 hours of completing surveys, 8 hours of completing PRT lessons, and at least 30 minutes a day of implementing PRT on your own over the course of the eight weeks (which adds up to about 28 hours total PRT on your own). The grand total number of hours is about 39 hours. Most of these hours will take place over about 8-9 weeks, plus the completion of final surveys and videos 2-3 months after the program has finished.

Future Contact: In the future, we may reach out to you again to check in on your child's long-term progress (for example, after a year). If you opt to complete our developmental surveys and parent-child videos during this follow-up, you will be compensated again.

Total Number of Participants: 48 families will be recruited nationwide to participate in this project.

Funding Source: This study is funded by the Department of Defense's Congressionally Directed Medical Research Programs - Autism Research Program.

Video Consent: By signing this consent form, you also agree to allow us to receive and analyze your PRT videos for research purposes (that is, to help us evaluate the impact of the PRT smartphone app).

Videos are typically stored indefinitely (forever) in a secure digital format. If you would prefer to have the videos deleted

at a future date instead, please indicate your preference by checking your preference here:

☐ Videos may be kept indefinitely (preferred)

☐ Videos should be destroyed after all data for the research project is collected and analyzed

In addition to using the videos for research purposes, you may also opt to allow our research team to use your videos for other purposes. Note: Please read the following options carefully and leave them blank if you do not wish to consent to them. **These options are completely voluntary, can be revoked by you at any time, and are NOT required to participate in this project:**

☐ My family's videotapes can be used in future, unspecified research projects by the UCSB Koegel Autism Center

☐ My family's videotapes can be used in future versions of this app or related PRT educational materials

☐ My family's videotapes can be shown during scientific presentations (research conferences).

☐ My family's videotapes can be shown in a classroom to undergraduate and graduate students

☐ My family's videotapes can be shown in public presentations to non-scientific groups (community trainings)

☐ My family's videotapes can be used on television (news broadcasts, documentaries)

☐ I am undecided; ask me again after I finish the project

ALTERNATIVES:

As an alternative to this project, you can seek out local autism intervention services from providers in your area. If you have current autism services (applied behavior analysis, speech, occupational/physical therapy, early intervention), you are welcome to continue with them while you also participate in this study. We encourage families to try to keep their current services the same during participation in this trial.

RISKS:

When initially exposed to the PRT strategies to promote social engagement and language use, some children become upset when encouraged to talk and interact, particularly in the beginning. PRT is designed to minimize this risk by using child-selected activities, playful exchanges, and highly motivating strategies to promote language use. Parents are also encouraged to try a different PRT activity, give the child a break, or stop for the day if a child is having difficulty. Parents are also free to withdraw from the project at any time without penalty.

You may also become concerned, distressed, or anxious if you do not feel like you are mastering the PRT strategies as fast as you anticipated, if your child does not respond to your PRT bids, and/or if your child does not make the gains as quickly as you expected in the areas of language, social engagement, or challenging behavior. These concerns are perfectly normal. The app features several components to help you troubleshoot things if you are having difficulty learning to use all of the components of PRT, including troubleshooting guides, frequently asked questions, and video examples. We also want to normalize that children with autism develop and improve at different rates. Continued use of PRT over several months is associated with improved child developmental outcomes. We also encourage you to seek out consultation from local autism providers should you need live support. Because we are evaluating the use of this training app as an educational tool, we are unable to provide in-person consultation and feedback during the trial.

There is the unlikely risk of identifying information being accessed by outside parties. This risk is minimized by having videos and other information encrypted before they are digitally sent to us, storing them on encrypted data storage programs, training all of our research staff in data security procedures, and limiting access to these files.

BENEFITS:

While not guaranteed, we anticipate that parents who participate in this project and use our new, experimental smartphone app will learn how to incorporate PRT strategies into their interactions with their child. When implemented consistently, PRT has been demonstrated to often increase child language skills, social engagement, and developmental competencies while decreasing autism symptom severity.

CONFIDENTIALITY

We take your confidentiality and privacy very seriously. We take several steps to ensure that your confidentiality and privacy are maintained during your participation in this study. The videos collected in this project cannot be stripped of your or your child's identifying information, so we take steps to ensure that they are not accessed by unauthorized parties. This risk of a data breach is minimized by having videos and other data encrypted before they are digitally sent to us, storing them on encrypted data storage programs, training all of our research staff in data security procedures, and limiting access to these files. Your developmental survey data will be stripped of identifying information (so no one can link it to you) so that it can be anonymously shared with other autism researchers on a nationwide database. These data (which cannot be linked back to you) may then be used or shared in future research studies without your consent.

Your app usage data, ratings of app satisfaction and usability, and written feedback comments will also be de-identified and shared with the app development company (Novacoast) to improve the PRT app for future use.

Absolute confidentiality cannot be guaranteed, since research documents are not protected from subpoena. Additionally, as mandated reporters for UCSB, we are required to report any suspected cases of child abuse or neglect to the appropriate authorities.

Because this research is being funded by the Department of Defense's Congressionally Directed Medical Research Programs - Autism Research Program, representatives of the DoD are authorized to review research records and associated private health information pertaining to this study

With your permission, your and your child's demographic and developmental survey data will be stripped of your names and other identifying information (so no one can link it back to you) so that it can be anonymously shared with other autism researchers on a nationwide database. No videos will be shared. These data may then be used or shared in future research studies without your consent.

Do you permit us to share your deidentified, anonymous data with the National Database for Autism Research?
___YES ___NO ___Undecided, Please Ask Me Later

COSTS/PAYMENT:

You will receive \$25 for completing the intake surveys and parent-child videos, \$5 for recording and submitting a PRT practice video with your child after each of the eight weekly lessons (\$40 total), and another \$25 when completing the developmental surveys and final parent-child videos, for a total possible compensation of \$90. If you withdraw from the project early, you will still receive compensation for the phases you completed. Payments are typically sent through digital payment platforms, such as Paypal or Venmo.

EMERGENCY CARE AND TREATMENT FOR INJURY:

If your child is injured as a direct result of research procedures, you will receive reasonably necessary medical treatment at no cost. The University of California does not provide any other form of compensation for injury.

RIGHT TO REFUSE OR WITHDRAW:

You and/or your child may refuse to participate and still receive any benefits your child would receive if he/she were not in the study. You may also change your mind about being in the study and remove yourself and your child from participation after the study has started.

PRINCIPAL INVESTIGATORS DISCLOSURE OF PERSONAL AND FINANCIAL INTERESTS IN THE RESEARCH AND STUDY PROGRAM:

The investigators of this project have no current personal or financial interests or conflicts related to this research, although this application may be commercialized in the future. Videos collected from you for this study and/or information obtained from these videos may be used in this research or related research by our team.

QUESTIONS:

If you have any questions about this research project or if you think you may have been injured as a result of your participation, please contact: Principal Investigator: Ty Vernon, Ph.D, 805-893-2049, tyvernon@ucsb.edu If you have any questions regarding your rights and participation as a research subject, please contact the Human Subjects Committee at (805) 893-3807 or hsc@research.ucsb.edu. Or write to the University of California, Human Subjects Committee, Office of Research, Santa Barbara, CA 93106-2050 You can access a copy of this consent form at any time through this app. If you would also like a copy of this consent emailed to you, please check here ____.